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EXAMINER	
YOUNG, JOSEPHINE	
ART UNIT	**PAPER NUMBER**
1623	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,413	Applicant(s) AUZELY-VELTY ET AL.	
	Examiner Josephine Young	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Amendment filed October 29, 2001

In the amendment filed October 29, 2001, claims 1-16 were cancelled. Claims 17-36 were added.

An action on the merits of claims 17-36 is contained herein below.

Specification

The abstract of the disclosure is objected to because it does not conform to the Abstract on the front page of the Patent Cooperation Treaty publication (i.e., pamphlet). See MPEP § 1893.03(e). Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 28 is objected to because of the following informalities: The bond connecting the azide moiety to the cyclodextrin of formula (IV) is missing. See page 7 of the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below in In re Wands USPQ2d 14000. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

These factors include

(1) quantity of experimentation necessary,

(2) the amount of guidance presented,

(3) the presence or absence of working examples,

(4) the nature of the invention,

(5) the state of the prior art,

(6) the predictability of the art and

(7) the breath of the claims.

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the obtaining a derivative of formula (VIII) wherein m is 2 and R^8 is OR^2 from the derivative according to formula (VI) wherein R^7 is OR^2 using the acid anhydride, succinic anhydride, does not reasonably provide enablement for obtaining a derivative of formula (VIII) using a compound according to the formula (VII). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine which peracid would be able to react with a derivative according to formula (VI) to form a derivative of formula (VIII) for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing and determining such, as only an acid anhydride, namely succinic anhydride, was used as a reagent.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, while certain acid anhydrides are known to react with amines to form amides with terminal carboxylic acids, no peracid has been found to react in the same way with amines to form amides with terminal carboxylic acids. Therefore, the art at the time the invention was made fails to establish predictability with regard to the properties of the peracid needed to perform the scope of the methods as instantly claimed.

With regard to factors (3) and (7), it is noted that while there is one working example of the conversion of a derivative according to formula (VI) to a derivative of formula (VIII) using succinic anhydride, it is not seen as sufficient to support the breath of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Further, claims 30-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inclusion complexes, nanoparticles and organized surfactant systems using mono-6-(cholest-5-en-3α-ylamide)succinylamide-6-deoxy-2,2',2'',2'''-2,'''',2''''',2''''''',6',6'',6''',6,'''',6''''',6''''''-trideca-O-methyl-cyclomaltoheptaose, does not

reasonably provide enablement for inclusion complexes, nanoparticles and organized surfactant systems using any other cyclodextrin derivative according to the formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine which cyclodextrin derivative would be able to form inclusion complexes, nanoparticles and organized surfactant systems for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing such, as only one cyclodextrin derivative according to the formula (I) was assessed for its ability to form inclusion complexes, nanoparticles and organized surfactant systems, out of the numerous possible cyclodextrin derivatives according to the formula (I).

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, β-cyclodextrin derivatives with aliphatic chains in the primary and secondary positions are amphiphilic and can be incorporated in vesicles, but the internal cavity of the cyclodextrin is no longer accessible due to the significant steric size of the aliphatic chains. See for example JULIEN et al., J. Chem. Soc. Perkin Trans 2, 1993, 1011-1022. The art at the time the invention was made fails to establish predictability with regard to the properties of the cyclodextrin derivatives needed to perform the methods as instantly claimed.

With regard to factors (3) and (7), it is noted that while there are some working examples of compositions comprising mono-6-(cholest-5-en-3α-ylamide)succinylamide-6-deoxy-2,2',2'',2''',2,'''',2''''',2'''''',6',6'',6''',6,'''',6''''',6''''''-trideca-O-methyl-

cyclomaltoheptaose, it is not seen as sufficient to support the breath of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19-22 and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "group derived from a steroid" in claims 17, 19-22 and 28-36 renders the claims in which it appears indefinite. In the absence of the specific modification to the steroid or distinct language to describe the structural modifications or the chemical names of the derivatized steroid of this invention, the identity of said group derived from a steroid would be difficult to describe and the metes and bounds of said group that Applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

The term "acid anhydride" in claims 28 and 29 renders the claims in which it appears indefinite. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The "acid anhydride" according to formula VII in claims 28 and 29 is

used by the claim to mean a peracid (i.e. a compound of general formula –C(=O)OO-), while the accepted meaning of an acid anhydride is a compound of general formula -C(=O)OC(=O)-.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 17-36 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by AUZELY-VELTY, R. et al. Langmuir, **2000**, *16*, 3727-3734 (A).

Because a translation of the foreign priority papers has not been made of record in accordance with 37 CFR 1.55, Applicant cannot rely upon the priority date of said papers. See MPEP § 201.15. To overcome this rejection, Applicant may submit a translation of the foreign priority papers in accordance with 37 CFR 1.55.

Alternatively, a declaration filed under 37 CFR 1.131 would be sufficient to overcome the AUZELY-VELTY (A) reference.

Claims 17-36 are rejected under 35 U.S.C. 102(a) as being anticipated by AUZELY-VELTY, Rachel et al. Carbohydrate Research, **31 May 1999**, *318*, 82-90 (B).

Because a translation of the foreign priority papers has not been made of record in accordance with 37 CFR 1.55, Applicant cannot rely upon the priority date of said papers. See

MPEP § 201.15. To overcome this rejection, Applicant may submit a translation of the foreign priority papers in accordance with 37 CFR 1.55.

Alternatively, a declaration filed under 37 CFR 1.131 would be sufficient to overcome the AUZELY-VELTY (B) reference.

Conclusion

Claims 17-36 are pending. Claims 17-36 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
April 29, 2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600